

§ 352.60

21 CFR Ch. I (4–1–08 Edition)

as needed” in § 352.52(d)(1) is not required.

(4) *For products marketed as a lip protectant or lipstick.* The directions in paragraphs (d)(1) and (d)(2) of this section are not required.

(e) *Statement on product performance—*

(1) *For products containing any ingredient identified in § 352.10, the following PCD labeling claims may be used under the heading “Other information” or anywhere outside of the “Drug Facts” box or enclosure.*

(i) *For products containing active ingredient(s) that provide an SPF value of 2 to under 12.* (Select one of the following: “minimal” or “minimum”) “sun protection product.”

(ii) *For products containing active ingredient(s) that provide an SPF value of 12 to under 30.* “moderate sun protection product.”

(iii) *For products containing active ingredient(s) that provide an SPF value of 30 or above.* “high sun protection product.”

(2) *For products containing any ingredient identified in § 352.10, the following labeling statement may be used under the heading “Other information” or anywhere outside of the “Drug Facts” box or enclosure.* “Sun alert: Limiting sun exposure, wearing protective clothing, and using sunscreens may reduce the risks of skin aging, skin cancer, and other harmful effects of the sun.” Any variation of this statement will cause the product to be misbranded under section 502 of the act.

(f) *Products labeled for use only on specific small areas of the face (e.g., lips, nose, ears, and/or around eyes) and that meet the criteria established in § 201.66(d)(10) of this chapter.* The title, headings, subheadings, and information described in § 201.66(c) of this chapter shall be printed in accordance with the following specifications:

(1) The labeling shall meet the requirements of § 201.66(c) of this chapter except that the title, headings, and information described in § 201.66(c)(1), (c)(3), and (c)(7) may be omitted, and the headings, subheadings, and information described in § 201.66(c)(2), (c)(4), (c)(5), and (c)(6) may be presented as follows:—

(i) The active ingredients (§ 201.66(c)(2) of this chapter) shall be listed in alphabetical order.

(ii) The heading and the indication required by § 201.66(c)(4) of this chapter may be limited to: “Use [in bold type] helps protect against sunburn.” For a lip protectant product, the heading and the indication required by § 201.66(c)(4) may be limited to: “Use [in bold type] helps protect against sunburn and chapped lips.”

(iii) The “external use only” warning in § 201.66(c)(5)(i) of this chapter may be omitted.

(iv) The subheadings in § 201.66(c)(5)(iii) through (c)(5)(vii) of this chapter may be omitted, provided the information after the heading “Warnings” states: “Keep out of eyes.” and “Stop use if skin rash occurs.”

(v) The warning in § 201.66(c)(5)(x) of this chapter may be limited to the following: “Keep out of reach of children.”

(vi) For a lip protectant product or lipstick, the warnings “Keep out of eyes” in § 352.52(f)(1)(iv) and “Keep out of reach of children” in § 352.52(f)(1)(v) and the directions in § 352.52(d) may be omitted.

(2) The labeling shall be printed in accordance with the requirements of § 201.66(d) of this chapter except that any requirements related to § 201.66(c)(1), (c)(3), and (c)(7), and the horizontal barlines and hairlines described in § 201.66(d)(8), may be omitted.

[64 FR 27687, May 21, 1999, as amended at 68 FR 33380, June 4, 2003]

§ 352.60 Labeling of permitted combinations of active ingredients.

Statements of identity, indications, warnings, and directions for use, respectively, applicable to each ingredient in the product may be combined to eliminate duplicative words or phrases so that the resulting information is clear and understandable.

(a) *Statement of identity.* For a combination drug product that has an established name, the labeling of the product states the established name of the combination drug product, followed by the statement of identity for each ingredient in the combination, as established in the statement of identity sections of the applicable OTC drug

monographs. For a combination drug product that does not have an established name, the labeling of the product states the statement of identity for each ingredient in the combination, as established in the statement of identity sections of the applicable OTC drug monographs.

(b) *Indications.* The labeling of the product states, under the heading “Uses,” the indication(s) for each ingredient in the combination as established in the indications sections of the applicable OTC drug monographs, unless otherwise stated in this paragraph. Other truthful and nonmisleading statements, describing only the indications for use that have been established in the applicable OTC drug monographs or listed in this paragraph (b), may also be used, as provided by § 330.1(c)(2) of this chapter, subject to the provisions of section 502 of the Federal Food, Drug, and Cosmetic Act (the act) relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(1) In addition, the labeling of the product may contain any of the “other allowable statements” that are identified in the applicable monographs.

(2) For permitted combinations containing a sunscreen and a skin protectant identified in § 352.20(b), any or all of the applicable indications for sunscreens in § 352.52(b) and the indication for skin protectants in § 347.50(b)(2)(i) of this chapter should be used. For products marketed as a lip protectant, the indication in § 352.52(f)(1)(ii) should be used.

(c) *Warnings.* The labeling of the product states, under the heading “Warnings,” the warning(s) for each ingredient in the combination, as established in the warnings section of the applicable OTC drug monographs, except that the warning for skin protectants in § 347.50(c)(3) of this chapter is not required for permitted combinations containing a sunscreen and a skin protectant identified in § 352.20(b). For products marketed as a lip protectant or lipstick, § 352.52(f)(1)(iii), (f)(1)(iv) (except “Keep out of eyes,”

which may be omitted), and (f)(1)(vi) apply.

(d) *Directions.* The labeling of the product states, under the heading “directions,” directions that conform to the directions established for each ingredient in the directions sections of the applicable OTC drug monographs, unless otherwise stated in this paragraph. When the time intervals or age limitations for administration of the individual ingredients differ, the directions for the combination product may not contain any dosage that exceeds those established for any individual ingredient in the applicable OTC drug monograph(s), and may not provide for use by any age group lower than the highest minimum age limit established for any individual ingredient. For permitted combinations containing a sunscreen and a skin protectant identified in § 352.20(b), the directions for sunscreens in § 352.52(d) should be used. For products marketed as a lip protectant or lipstick, § 352.52(d)(4) applies.

[64 FR 27687, May 21, 1999, as amended at 68 FR 33380, June 4, 2003]

Subpart D—Testing Procedures

§ 352.70 Standard sunscreen.

(a) *Laboratory validation.* A standard sunscreen shall be used concomitantly in the testing procedures for determining the SPF value of a sunscreen drug product to ensure the uniform evaluation of sunscreen drug products. The standard sunscreen shall be an 8-percent homosalate preparation with a mean SPF value of 4.47 (standard deviation =1.279). In order for the SPF determination of a test product to be considered valid, the SPF of the standard sunscreen must fall within the standard deviation range of the expected SPF (i.e., 4.47 ± 1.279) and the 95-percent confidence interval for the mean SPF must contain the value 4.

(b) *Preparation of the standard homosalate sunscreen.* (1) The standard homosalate sunscreen is prepared from two different preparations (preparation A and preparation B) with the following compositions: